

- Protect from damage, loose debris, dust, frost and direct sunlight.
- During First time use, after storage and minimally on a semi-annual basis, perform Functional check (See Section 3.0).

5.0 CLEANING and SPECIAL INSTRUCTIONS

5.1 CLEANING

The DUPLOSPRAY MIS Regulator housing, Foot Switch, and hoses can be cleaned with many hospital approved (pH 7 neutral) disinfectants.

In order for the device to operate safely and in accordance with the intended use, the Regulator must be cleaned, following each use, maintained free of dirt and other debris.

5.2 SPECIAL INSTRUCTIONS

- CAUTION: Do not use high pH (acid) or low pH (caustic cleansers)
- CAUTION: Do not allow cleaning solution to enter Patient Vent (3) or Gas Outlet (5) fittings on front panel. Use Luer caps or cover fittings with a lint free cloth.
- CAUTION: Do not allow cleaning solution to enter the Gas (DISS Female CO₂) connection (1); cover with a lint free cloth.
- CAUTION: Do not allow disinfectants to pool anywhere on the device such as on Flow Meter (4).
- CAUTION: Do not immerse or soak the entire unit.
- CAUTION: Do not use abrasive pads or cleansers.
- CAUTION: Do not process in automatic washer or steam sterilizer.

6.0 REGULATOR REPAIR AND MAINTENANCE

DUPLOSPRAY MIS Regulator internal components are not user serviceable.

6.1 FUNCTIONAL CHECK

On a semi-annual basis, the DUPLOSPRAY MIS Regulator should be checked for proper operation by performing a functional check (See 3.0 Functional Check).

6.2 MAINTENANCE CHECK

A maintenance check should be performed on the DUPLOSPRAY MIS Regulator on an annual basis.

6.3 MAINTENANCE SET UP

- Attach Gas (DISS Female CO₂) Connection (1) to CO₂ gas source and set gas supply pressure to 100psi \pm 5 (6.89 bar \pm .35).
- Place Foot Switch (2) flat in convenient location.
- While depressing Foot Switch (2), turn Flow Control Knob, (6), clockwise and adjust flow to 10 L/min as indicated on Flow Meter, (4).
- Connect a calibrated 0 – 30 psi pressure gauge to the Gas Outlet (5).
- While depressing the Foot switch (2), verify calibrated pressure gauge reading agree to 19psi \pm 2 (1.31 bar \pm .13). Flow gauge should indicate 0 L/min after a momentary jump.

- Remove calibrated pressure gauge.

6.4 VERIFY REGULATOR FLOW

- While depressing Foot Switch (2), turn Flow Control Knob (6), clockwise and back and verify flow is adjustable from 0 to 10 L/min minimum and indicated by the Flow Meter (4).
- With foot switch (2) released verify flow Meter ball (4) does not stick at top of Flow Meter.
- Connect a calibrated flow meter for CO₂ with a range of 0 - 10 L/min with an accuracy of 2% full scale to the Gas Outlet (5).
- While depressing foot switch (2), turn Flow Control Knob (6) to read 2 L/min on Flow Meter (4).
- The flow on the calibrated flow meter should verify 2 L/min flow within \pm .5 L/min.
- Remove calibrated flow meter from Gas Outlet (5).

6.5 VERIFY PATIENT VENT

- Connect the tubing set from the DUPLOSPRAY MIS Applicator to Gas outlet (5) and Patient Vent (3). Join the Male/Female Luer connections on the distal end of the tubing set.
Note: A short single lumen tube set with appropriate Male/Female Luer connections may be a substituted for the above.
- While depressing Foot Switch (2), turn Flow Control Knob, (6), clockwise and adjust flow to 5 L/min as indicated on Flow Meter (4).
- With Foot Switch (2) released, gas flow must stop and Flow Meter (4) goes to zero.
- Remove Tubing set from Gas Outlet (5) and Patient Vent (3).

6.6 CHECK FOR LEAKS

- While depressing Foot Switch (2), turn Flow Control Knob (6) to read 5 L/min on Flow Meter (4).
- Block Gas Outlet (5) with a luer cap, check for internal leaks by observing the movement of Flow Meter (4) ball. The ball will remain at zero (after a momentary jump) if free of leaks.
- Remove Luer Cap from Gas Outlet (5).

6.7 SAFETY RELIEF VALVE OPERATION

CAUTION: Pressure above 22 psi (1.5 Bar) will cause the Regulator's internal safety relief valve to vent excess gas inside Regulator housing with an audible signal.

Should the Safety relief valve actuate at anytime:

- Confirm incoming gas supply pressure to the device is set correctly to 100 psi \pm 5 (6.89 bar \pm .35).
- Should the Safety relief valve continue to actuate after the device input pressure is confirmed to be correct:
 - Immediately remove MIS Regulator from service.
 - Call Baxter Customer Service using the contact information shown on the base of the device or contact your local Baxter representative.

7.0 TERMS OF WARRANTY

The manufacturer warrants devices against all defects in material and workmanship that occur within one (1) year after the date of sale.

Warranty claims will be processed by the Manufacturer under the following conditions:

- Inform Baxter immediately of malfunction. Please provide the serial number of the device when reporting.
- Observe all instructions regarding storage and return of the device.
- Present a legible copy of the invoice for the device in question, which clearly shows date of sale.
- Describe in as much detail as possible suspected defects or malfunctions experienced by user.

ATTENTION: The warranty will not be applicable if warnings, intended use, and cleaning instructions for the device are not followed as stated herein.

The manufacturer and the supplier of the device deny liability, if:

- The device is not used in accordance with instruction manual.
- The defect was not caused by manufacturer or persons and service companies authorized by manufacturer.

8.0 RETURN OF DEVICES

Reasons for return:

1. Results of the first-time use are unsatisfactory/unsafe.
2. Defective device

Call Baxter Customer Service using the contact information shown on the base of the device or contact your local Baxter representative to obtain a Return Authorization (RA) Number prior to returning. Product returns not accepted without a Return Authorization number.

When returning a device, clean it carefully and pack it in the original package. If the original package is no longer available, request appropriate packaging through Baxter customer service using contact information on base of device or contact your local Baxter representative.

9.0 DISPOSAL OF DEVICES

The DUPLOSPRAY MIS Regulator has no electrical components or hazardous materials in its construction.

Clean the DUPLOSPRAY MIS Regulator to remove any potential biohazard contamination prior to disposal.

- Do not dispose of DUPLOSPRAY MIS Regulator as unsorted municipal waste.
- Collect DUPLOSPRAY MIS Regulator separately as Used Medical Waste.
- Use collection and return systems available to you.

For more information on return, recovery or recycling of DUPLOSPRAY MIS Regulator, contact your local Baxter representative.